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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,735	09/09/2003	Antoni Kozlowski	SHE0064.00	3908
21968	7590	08/07/2007		
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			08/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/659,735

Applicant(s)

KOZLOWSKI, ANTONI

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-27, 31-37, 45, 50, 51 and 55-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-30, 38-44, 46-49 and 52-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/26/07 &amp; 3/09/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 4/23/07. Claims 28 and 52 are amended. Claims 1-85 are pending. Claims 1-27, 31-37, 45, 50, 51 and 55-85 are withdrawn from consideration.

#### ***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

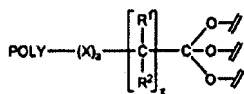
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 28-30, 38-44, 46-49 and 54-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the ortho ester moiety generally represented in claim 52 with R<sup>4</sup>'s defined as noted in claim 52, does not reasonably provide enablement for a moiety of the type represented in claim 28 where the oxygen atom is bonded to any carbon containing species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is scope of enablement.

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Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all the factors are considered, a sufficient number of the factors are discussed below for a prima facie case.

**The Nature of the Invention:** The invention in generic claim 28 is directed to a polymer that has the structure depicted in the claim 28 as



where Poly, X, z, a, R<sup>1</sup> and R<sup>2</sup> are all defined, and where the oxygen is attached to any carbon containing moiety.

**The amount of guidance or direction presented:** Specific ortho ester moiety as



represented by does not include all the possibilities of the moiety when the oxygen is bonded to all carbon-containing moieties. For example, the polymers listed in paragraph [0196] of the published application do not meet the full scope of the polymer recited in claim 28 so that every polymer within the scope of the polymer in claim 28 is not enabled. It is noted that, the Federal Circuit in “In re Wright” held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue

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experimentation.” In the present case, the specification does not teach how to make and use the full scope of the invention in the polymer of claim 28.

**Quantity of Experimentation:** Therefore, since guidance is limited to the polymers disclosed/listed in the specification and not to the full scope of the polymer of the claim 28, it would require undue experimentation on the artisan to practice the full scope of the invention.

Specifically, the moiety,



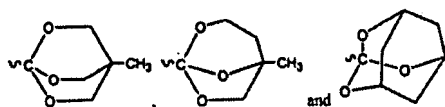
is open-ended requiring the ortho ester to have any carbon-containing moiety bonded to the oxygen atoms. Since what is disclosed does not meet the full scope of what is claimed, the scope of enablement provided to one skilled in the art by the disclosure is not commensurate with the scope of protection sought by the claims.

Thus in view of the above, it is noted that the claims are broader than what is disclosed to the polymer of claim 28 and specifically with respect to the ortho ester moiety

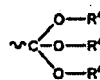


and one skilled in the art is not enabled to practice the full scope of the claimed invention without undue experimentation.

The rejection can be overcome by replacing moieties in claim 54, which is



or



for




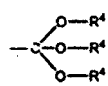
in the polymer

of claim 28.

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4. Claims 28-30, 38-44, 46-49 and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The meets and bounds of  in the polymer of claim 28 is not known.

The claims are examined as having the polymer having  as the ortho ester moiety where R4 is an alkyl group having 1-6 carbons, methyl or ethyl ortho acetate, low molecular weight ortho esters that are commercially available (see Bergstrom at page 4, lines 11-35)

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 28-30, 38-42, 46, 47, 49, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al. (WO 99/32424).

Bergstrom discloses ortho ester based surfactants where ortho ester linkages (page 1, lines 3-8) connect the hydrophobic and hydrophilic parts; the ortho ester portion is represented by formula (II) (page 4, lines 13-16 representing the moiety of claims 52, 53, 28. The hydrophilic part of the molecule is derived from polyethylene glycols that are end-capped having

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molecular weight of between 100 and 2000 (page 5, lines 9-14) meeting the "Poly—" of the polymer of claims 28, 38-41, 46, 47 and 48. Therefore, Bergstrom meets the claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 28, 42-44 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrom et al. (WO 99/32424) in view of Hunter et al. (US 5763538) and Baker (US 5,634,971).

Bergstrom is described above. Regarding claim 54, which is directed to cyclic form of the ortho ester moiety, it is noted that one ortho ester can be used in place of the other and expect both polymers, one with the moiety of Bergstrom and the other having another moiety such as the cyclic ortho ester, to be drug delivery vehicles and other uses. The polyethylene glycol portion of the polymer of Bergstrom is end-capped with alkyl groups such as methyl and ethyl. Bergstrom does not cap the polyethylene glycol with alkoxy groups as is recited in claims 42-44. However, it is known in the art that alkyl, such as methyl and alkoxy such as ethoxy and methoxy are used to end-cap polyethylene glycol and the teachings of Hunter and Baker; Hunter teaches polyethylene glycol that is end-capped with methoxy or ethoxy (column 2, lines 44 and 45; claims 5 and 7); Baker teaches end-capping polyethylene glycol with methyl groups. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polymer of Bergstrom having methyl end-capped polyethylene glycol. One

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having ordinary skill in the art would have used alkoxy-end-capped polyethylene glycol and expect the effects of both polymers to be unaltered in the delivery of active agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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